# THE EPIDEMIOLOGY AND OUTCOMES OF BREAST CANCER SURGERY

VICTORIA J. FRASER, MD, and *(by invitation)* KATELIN B. NICKEL, MPH, IDA K. FOX, MD, JULIE A. MARGENTHALER, MD, and MARGARET A. OLSEN, PHD

ST. LOUIS, MISSOURI

## ABSTRACT

We studied women after breast-conserving surgery and mastectomy with immediate (IR) and delayed reconstruction to determine the risk of surgical site infections (SSIs). The SSI rate was 1.3% for BCS, 5.2% for mastectomy, and 10.3% for mastectomy plus IR with flap. SSI risk was higher for mastectomy and IR with implantation versus delayed reconstruction with implantation (8.8% versus 5.9%, $P = 0.039$) or staged reconstruction with implantation (3.3%, $P < 0.001$). Women with SSI had more SSIs after second-staged reconstruction and implantation compared to those without SSI (10.9% versus 2.7%, $P < 0.001$). SSI was first coded 2 to 30 days postoperatively in 50.3%, and 23% between 31 and 60 days postoperatively. The noninfectious wound complication rate was 10.8%. The noninfectious wound complication rate was 5.8% after mastectomy, 13.4% after mastectomy with implantation, 18.7% after mastectomy with flap, and 15.2% with mastectomy flap and implantation ($P < 0.001$). Implants were removed within 60 days in 6% of mastectomies with implantation.

## INTRODUCTION

Breast cancer is one of the most common malignancies occurring worldwide. Approximately 12% of women develop breast cancer. There were 231,840 new cases of breast cancer identified in the United States in 2015 (1). There are approximately 2.975 million women living with breast cancer in the United States today (1). Thus, breast cancer and its associated treatments and complications are an important public health issue. Specific treatment for breast cancer depends on the stage and type of tumor; however, generally, breast cancer therapy is multidisciplinary and includes surgery, radiation, and chemotherapy. Surgical approaches for the treatment of breast cancer are typically

Correspondence and reprint requests: Victoria J. Fraser, MD, Adolphus Busch Professor of Medicine, Washington University School of Medicine, Campus Box 8066, 660 South Euclid Avenue, St. Louis, MO 63110, Tel: 314-362-8061, Fax: 314-862-8015, E-mail: vfraser@wustl.edu.

Potential Conflicts of Interest: None disclosed.



BK-ACC-ACCA_2016-160073-Fraser.indd 46 29/06/16 5:16 PM

performed by surgical oncologists or breast surgeons with general surgery training. Breast cancer surgery includes breast-conserving surgery (BCS), sometimes referred to as lumpectomy, and more complete removal of all breast tissue termed mastectomy. BCS is the most common surgical treatment of early-stage breast cancer. Re-excision is required in 10% to 40% of women with breast cancer because a clear pathological margin may not always be obtained after initial surgery (2–6). Surgical reconstruction of the breast is typically performed by plastic surgeons. Breast reconstruction can be performed shortly after the time of the mastectomy, which is termed immediate reconstruction (IR). Reconstruction of the breast after mastectomy can also be postponed and performed at a later time after other cancer therapy is completed or underway, in which case it is called delayed reconstruction (DR). Breast reconstruction can be performed using prosthetic implants and/or muscle flaps. Some reconstructions involve multiple stages with implants and tissue expanders used in preparation for the definitive reconstruction.

Decisions regarding types and timing of breast reconstructions are often coupled with complex decisions about the treatment of the cancer which understandably takes precedence. The type of breast surgery and the type and timing of breast reconstruction can have important consequences for women, which can ultimately impact the timing and definitive treatment for their breast cancer. There are few studies that compare the outcomes of BCS, IR versus DR, and second-staged reconstruction. In contrast to breast cancer treatment trials which are generally rigorously designed randomized controlled studies, many of the breast cancer surgical outcomes reports are relatively small case series, cohorts, and case control studies which do not distinguish between the different types of surgeries or adequately account for comorbidities. Most of the existing data on the surgical outcomes of these various procedures comes from single-center reports (7–14).

It is important to study the actual risk of surgical site infectious and noninfectious wound complications (NIWC) after breast cancer surgery and breast reconstruction because these complications can lead to loss of the implant and/or tissue and muscle flap, poor cosmetic results, and increased surgical procedures. Surgical site infections (SSIs) and NIWCs also lead to increased morbidity, healthcare use, and costs (4,15–17). Breast surgery is typically categorized as “clean” surgery, a term used to identify types of surgeries with the lowest risk of bacterial contamination and likelihood to develop wound infections. Most clean surgeries carry an expected SSI risk of 1% to 2%, but actual SSI rates reported in the literature for breast surgery are much higher

BK-ACC-ACCA_2016-160073-Fraser.indd 47 29/06/16 5:16 PM

(5,14,18,19). For tracking and reporting breast SSI rates, the Centers for Disease Control and Prevention's (CDC) National Healthcare Surveillance Network tracks SSI rates nationally at more than 14,500 facilities. The CDC classifies all the different types of breast surgeries together including cancer and non-cancer surgeries, mastectomy, and BCS (20,21). This is problematic as public reporting of surgical outcomes may not be accurate if the data are not adequately risk adjusted based on the types of surgeries performed or the patients' comorbidities. Currently, there is no widely accepted or well-validated system to risk stratify an individual woman's probability of developing an SSI after breast surgery (22).

Although SSIs are the most common potential postoperative surgical complication, NIWCs can also occur that may negatively impact patient outcomes. The most common NIWCs after breast surgery are hematomas, wound dehiscence, and necrosis. NIWCs can lead to additional procedures, increased healthcare costs, and may delay definitive cancer therapies (10,23–25). Currently, there is no national surveillance or publicly reported data tracking NIWCs such as hematoma, dehiscence, or wound or skin, muscle, or fat necrosis after breast surgery. Only the American College of Surgeons National Surgical Quality Improvement Program collects data on wound dehiscence and loss of the flap or implant at 30 days postoperatively (26,27).

## METHODS

We established a large retrospective cohort of women from 18 to 64 years of age with mastectomy and breast reconstruction from January 1, 2004, through December 31, 2011, using commercial claims data from the Healthcare Integrated Research Database. A subset of patients from between June 29, 2004, and December 31, 2011, was used for the analysis of complications after BCS. Healthcare Integrated Research Database includes individuals from 12 Anthem-affiliated plans (California, Connecticut, Georgia, Indiana, Kentucky, Maine, Missouri, Nevada, New Hampshire, Ney York, Ohio, and Virginia) with fully adjudicated claims submitted from providers, facilities, and outpatient pharmacies linked to health plan enrollment information. Fully insured women with enrollment in a fee-for-service plan with medical coverage were eligible for inclusion. We required prior insurance plan enrollment for at least 180 days to establish the timing of the index surgery. We excluded women with end-stage renal disease,

BK-ACC-ACCA_2016-160073-Fraser.indd 48 29/06/16 5:16 PM

organ transplant, and HIV infection. International Classification of Diseases Ninth Revision Clinical Modification diagnosis codes and/or Current Procedure Terminology – 4 procedure codes from inpatient and outpatient facilities and provider claims were used to identify surgical procedures and complications within 180 days after surgery. Specific codes used to identify surgical procedures and complications have been previously described (18,28,29). The date of onset of SSIs and NIWCs was defined according to the timing and location of diagnosis. Pre-existing infections were identified and not counted with postoperative complications. Reconstruction at the time of mastectomy was considered immediate (IR); reconstruction >7 days after mastectomy was considered delayed (DR). Follow-up reconstructive procedures in women who had IR were considered second-stage reconstruction.

The rates of SSIs and NIWCs overall and by type of complication within 180 days after surgery with mastectomy, BCS, and IR and DR after mastectomy were compared using a chi-square test as were other categorical variable comparisons. To compare wound complication rates by type of procedure, the alpha was adjusted for multiple testing using the Bonferroni method. We used the Kruskal-Wallis test to compare continuous variables. All data management and statistical analyses were performed using SAS version 9.3 (SAS Institute Inc, Cary, NC). This study was approved by the Washington University Human Research Protection Office.

## RESULTS

Overall, 23,001 women with 28,827 BCSs were identified. Approximately 77% of women (17,659) had one BCS, 21.3% (4892) had two procedures, and 2% (450) had three or more BCS procedures within 180 days of the index BCS. Twenty-three percent of women had more than one BCS. SSIs were identified in 560 procedures (1.94%). The incidence of SSI was 1.82% for the index BCS, 2.4% for the second BCS, and 2.48% for the third BCS ($P = 0.002$). Figure 1 demonstrates the risk of SSIs in patients undergoing BCS with and without invasive cancer. The risk of SSI associated with re-excision remained significantly higher when the population was restricted to women with invasive breast cancer (2.56% versus 1.89%, $P = 0.002$). In women without invasive cancer, the SSI was 1% for the first BCS versus 1.89% for women with invasive cancer ($P < 0.001$). Figure 2 shows the time to identification of SSI in BCS. Typically, SSIs are only tracked for

BK-ACC-ACCA_2016-160073-Fraser.indd 49 29/06/16 5:16 PM

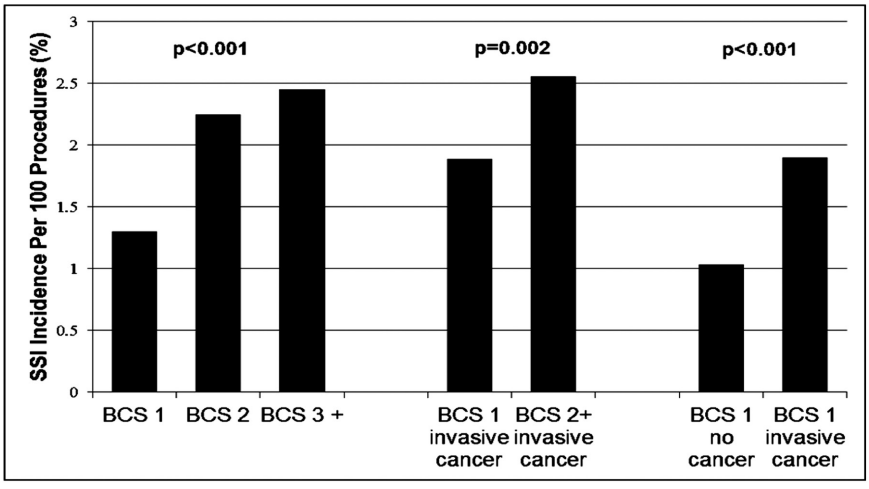


FIG. 1. Surgical site infection (SSI) risk by number of breast-conserving surgical (BCS) procedures with and without invasive cancer. Of 23,001 women with 28,827 BCS, 23% had >1 BCS. (HealthCore BC-BS data, 2004–2010.)

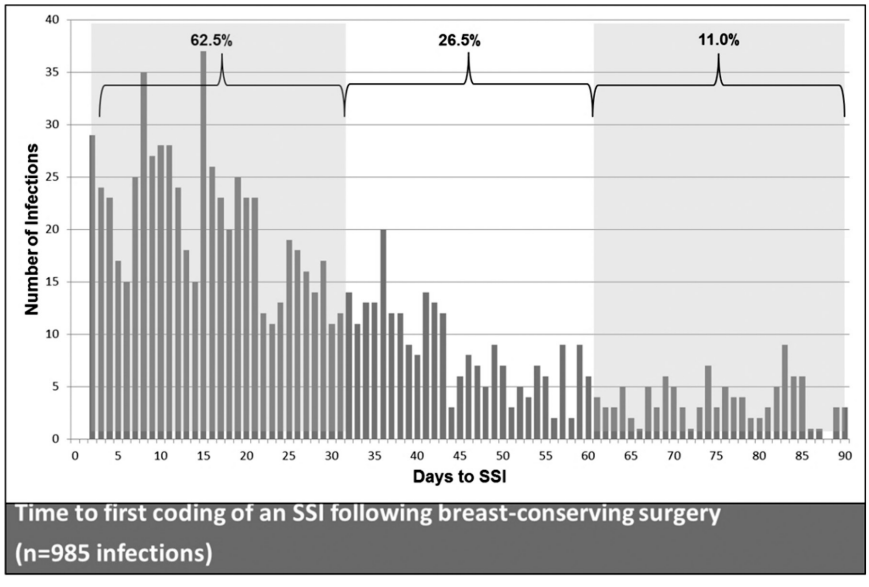


FIG. 2. Surgical site infection (SSI) surveillance and time of SSI diagnosis in breast-conserving surgery.

BK-ACC-ACCA_2016-160073-Fraser.indd 50 29/06/16 5:16 PM

30 days postoperatively unless there is an implant in place. Almost 58% of SSIs were identified within 30 days after BCS (n = 324), 115 (20.5%) were identified 31 to 45 days after surgery, 53 (9.5%) were identified 46 to 60 days after surgery, and 68 (12.1%) were identified 61 to 90 days after surgery.

For patients undergoing mastectomy, breast reconstruction is increasingly performed at the time of mastectomy. Reconstruction is often recommended because it is believed to confer long-term psychosocial benefits. The true impact on quality of life in women who have mastectomy only versus mastectomy with immediate reconstruction is difficult to assess because women who undergo mastectomy without reconstruction tend to be older, in stable relationships, Caucasian, and place less value on body image than women who undergo immediate reconstruction. The literature has suggested that there is no significant difference in SSI risk between immediate reconstruction and delayed implant or flap reconstruction, but most existing data are single-center studies with small sample sizes. Figure 3 shows the SSI incidence by type of mastectomy with and without immediate reconstruction. The SSI risk with mastectomy alone was 9.6% for mastectomy plus implant and 10.6% for mastectomy plus flap. Figure 4 shows the time of SSI diagnosis after mastectomy with and without immediate reconstruction. Only 50.3% of SSIs were identified within 30 days postoperatively. Approximately 33% were identified between 31 and 90 days postoperatively and almost 17% were identified after 90 days. Immediate reconstruction with an implant was associated with increased SSI risk compared to a delayed implant procedure (8.9% versus 5.9%, $P = 0.031$); however, there was no significant difference between index mastectomy and flap reconstruction SSI incidence (9.6%), delayed flap procedure surgical site infection incidence (10.6%), and second-stage flap procedure SSI incidence (9.5%) (Table 1).

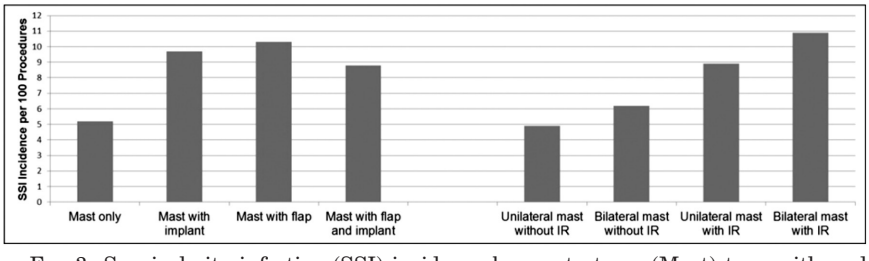


FIG. 3. Surgical site infection (SSI) incidence by mastectomy (Mast) type with and without immediate reconstruction (IR).

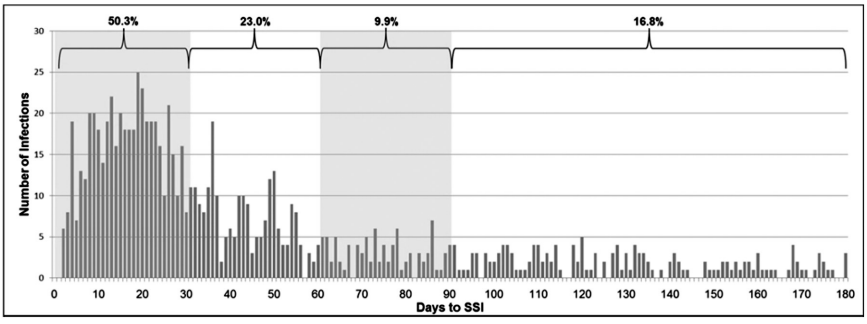


FIG. 4. Time of surgical site infection (SSI) diagnosis after mastectomy with and without immediate reconstruction.

The incidence of NIWCs after mastectomy alone, mastectomy with implant, mastectomy with flap, and mastectomy with flap and implant is presented in Table 2. The relative risk of any NIWC was higher for mastectomy and implant (1.77 [confidence interval (CI) 1.59, 1.98]) and mastectomy and flap (3.0 [CI 2.63, 3.42]) compared to mastectomy alone. Bilateral mastectomy and bilateral mastectomy and reconstruction also had higher relative risk of any NIWC than unilateral mastectomy alone or with reconstruction. The time to identification of NIWCs is presented in Figure 5. Approximately 58% of NIWCs were identified within 30 days and an additional 20% were identified between 31 and 60 days. Of 8,894 patients, 525 (5.9%) had early implant removal; 42.7% were due to surgical site infections, 17.3% were due to SSI and NIWC, and 9.3% were due to NIWCs. Mechanical complications accounted for 30.7% of early implant removal as shown in Table 3.

TABLE 1.
*Incidence of Surgical Site Infection After Immediate, Delayed, and Second-stage Breast Reconstruction*

| | N | SSI n (%) | *P*[a] |
|---|---|---|---|
| **Implant-based reconstruction** | | | |
| Index mastectomy + implant | **7,655** | **685 (8.9)** | **0.031** |
| Delayed implant | **424** | **25 (5.9)** | |
| **Flap-based reconstruction** | | | |
| **Index mastectomy + flap** | **2,392** | **229 (9.6)** | **0.902** |
| **Delayed flap** | **199** | **21 (10.6)** | |
| **Second-stage flap** | **179** | **17 (9.5)** | |

[a] *P* per chi-square test.

BK-ACC-ACCA_2016-160073-Fraser.indd 52 29/06/16 5:16 PM

TABLE 2.
*Incidence of Noninfectious Wound Complication*

| Operative Category | Total N | NIWC Requiring Surgical Wound Care | Any NIWC | Relative Risk of Any NIWC (95% Confidence Interval) |
|---|---|---|---|---|
| Mastectomy-only | 7,860 | 236 (3.0%) | 455 (5.8%) | 1.00 |
| Mastectomy + implant | 8,217 | 504 (6.1%) | 843 (10.3%) | 1.77 (1.59, 1.98) |
| Mastectomy + flap | 1,942 | 162 (8.3%) | 337 (17.4%) | 3.00 (2.63, 3.42) |
| Mastectomy + flap and implant | 677 | 47 (6.9%) | 79 (11.7%) | 2.02 (1.61, 2.53) |
| Unilateral mastectomy-only | 6,121 | 159 (2.6%) | 314 (5.1%) | 1.00 |
| Bilateral mastectomy-only | 1,739 | 77 (4.4%) | 141 (8.1%) | 1.58 (1.31, 1.91) |
| Unilateral mastectomy + reconstruction | 5,307 | 313 (5.9%) | 556 (10.5%) | 1.00 |
| Bilateral mastectomy + reconstruction | 5,529 | 400 (7.2%) | 703 (12.7%) | 1.21 (1.09, 1.35) |

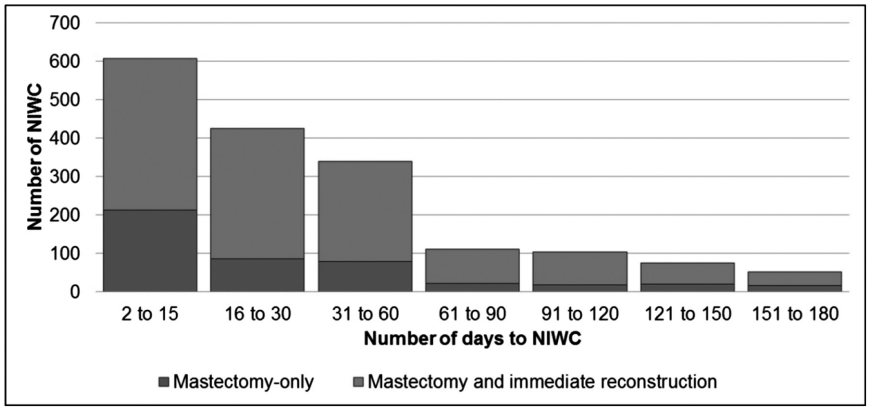


FIG. 5. Days to noninfections wound complication (NIWC) after mastectomy (n = 1,714 NIWCs).

TABLE 3.
*Early Implant Removal (Within 60 days)*

| | |
|---|---|
| **Mastectomy + implant** | **8,894** |
| **Early implant removal** | **525 (5.9%)** |
| **Reason for removal** | |
| Non-infectious wound complication (NIWC) | 49 (9.3%) |
| Surgical site infection (SSI) | 224 (42.7%) |
| **NIWC + SSI** | **91 (17.3%)** |
| Others (e.g., mechanical complications) | 161 (30.7%) |

BK-ACC-ACCA_2016-160073-Fraser.indd 53 29/06/16 5:16 PM

## DISCUSSION

SSIs increase with the number of BCS procedures performed and the presence of invasive cancer. SSI rates were also higher after immediate implant versus delayed or second-stage reconstruction. The timing of flap reconstructions was not significantly different for immediate versus delayed procedures. Half of SSIs and NIWCs were identified more than 30 days postoperatively. The incidence of NIWCs after mastectomy was almost 10%. This incidence of NIWCs was higher after mastectomy with reconstruction and higher with immediate flap reconstruction. Six percent of patients had early implant removal within 60 days of their initial procedures.

This study has several imitations. The use of claims data involves secondary analysis of data collected for billing purposes. There is potential for misclassification bias in the type of surgery, cancer diagnosis, procedure type, and likely under-coding of SSIs, particularly minor infections during the 90 day global surgical reimbursement period. The net result is likely toward the null and thus our findings of increased SSI risk associated with re-excision BCS and invasive cancer is probably a conservative estimate of the true effect. An additional limitation is the timing of SSI and NIWCs. Although the onset of SSI symptoms can often be captured in clinical data, in claims data SSI and NIWCs cannot be detected until the date of the first paid claim coded for infection or NIWCs.

The strengths of this study include the very large number of women and procedures studied in multiple geographically diverse surgical facilities. We used rigorous algorithms to identify SSIs and NIWCs. Claims data also allowed identification of SSIs and NIWCs across the spectrum of care including outpatient settings which are often missed by hospital-based infection surveillance programs. These data have clinical relevance to women and their physicians. Breast surgery complications have important consequences including loss of the implant and/or flaps, delays in chemotherapy and radiation, and increased risk of additional surgeries. Delays in chemotherapy and radiation therapy can ultimately impact women's survival, success of cancer therapy, and risk of cancer recurrence. Future studies will focus on developing risk prediction modeling to provide patients and doctors with specific data on each individual's risk of SSIs and NIWCs so they may make more informed decisions about the type and timing of their surgical reconstruction.

BK-ACC-ACCA_2016-160073-Fraser.indd 54 29/06/16 5:16 PM

## ACKNOWLEGMENTS

Funding for this research was provided by the CDC Epicenters Programs U54CK000162 to VJF and NIH 5R01CA149614 to Margaret Olsen. The findings and conclusions presented here are those of the authors and do not necessarily represent the views of the funding agencies (CDC or NIH).

## REFERENCES

1. American Cancer Society. *Breast Cancer Facts & Figures 2015–2016.* Atlanta, Georgia: American Cancer Society; 2015.
2. Jung W, Kang E, Kim SM, et al. Factors associated with re-excision after breast-conserving surgery for early-stage breast cancer. *J Breast Cancer* 2012;15(4): 412–9.
3. McCahill LE, Single RM, Aiello Bowles EJ, et al. Variability in reexcision following breast conservation surgery. *JAMA* 2012;307(5):467–75.
4. de Camargo CM, Comber H, Sharp L. Hospital and surgeon caseload are associated with risk of re-operation following breast-conserving surgery. *Breast Cancer Res Treat* 2013;140(3):535–44.
5. Seltzer MH. Partial mastectomy and limited axillary dissection performed as a same day surgical procedure in the treatment of breast cancer. *Int Surg* 1995;80(1):79–81.
6. Keidan RD, Hoffman JP, Weese JL, et al. Delayed breast abscesses after lumpectomy and radiation therapy. *Am Surg* 1990;56(7):440–4.
7. Nahabedian MY. AlloDerm performance in the setting of prosthetic breast surgery, infection, and irradiation. *Plast Reconstr Surg* 2009;124(6):1743–53.
8. Vilar-Compte D, Rosales S, Hernandez-Mello N, et al. Surveillance, control, and prevention of surgical site infections in breast cancer surgery: a 5-year experience. *Am J Infect Control* 2009;37(8):674–9.
9. Arver B, Isaksson K, Atterhem H, et al. Bilateral prophylactic mastectomy in Swedish women at high risk of breast cancer: a national survey. *Ann Surg* 2011;253(6):1147–54.
10. Davis GB, Peric M, Chan LS, et al. Identifying risk factors for surgical site infections in mastectomy patients using the National Surgical Quality Improvement Program database. *Am J Surg* 2013;205(2):194–9.
11. Ogunleye AA, de Blacam C, Curtis MS, et al. An analysis of delayed breast reconstruction outcomes as recorded in the American College of Surgeons National Surgical Quality Improvement Program. J Plast Reconstr Aesthet Surg 2012;65(3):289–94.
12. Chen J, Gutkin Z, Bawnik J. Postoperative infections in breast surgery. *J Hosp Infect* 1991;17(1):61–5.
13. Lipshy KA, Neifeld JP, Boyle RM, et al. Complications of mastectomy and their relationship to biopsy technique. Ann Surg Oncol 1996;3(3):290–4.
14. Van Geel AN, Contant CM, Wai RT, et al. Mastectomy by inverted drip incision and immediate reconstruction: data from 510 cases. *Ann Surg Oncol* 2003;10(4):389–95.
15. Jagsi R, Li Y, Morrow M, et al. Patient-reported quality of life and satisfaction with cosmetic outcomes after breast conservation and mastectomy with and without reconstruction: results of a survey of breast cancer survivors. *Ann Surg* 2015;261(6):1198–206.
16. Olsen MA, Chu-Ongsakul S, Brandt KE, et al. Hospital-associated costs due to surgical site infection after breast surgery. Arch Surg 2008;143(1):53–60.
17. Olsen MA, Lefta M, Dietz JR, et al. Risk factors for surgical site infection after major breast operation. J Am Coll Surg 2008;207(3):326–35.

BK-ACC-ACCA_2016-160073-Fraser.indd 55 29/06/16 5:16 PM

18. Olsen MA, Nickel KB, Fox IK, et al. Incidence of surgical site infection following mastectomy with and without immediate reconstruction using private insurer claims data. *Infect Control Hosp Epidemiol* 2015;36(8):907–14.
19. Alderman AK, Wilkins EG, Kim HM, et al. Complications in postmastectomy breast reconstruction: two-year results of the Michigan Breast Reconstruction Outcome Study. *Plast Reconstr Surg* 2002;109(7):2265–74.
20. Centers for Disease Control and Prevention. National Healthcare Safety Network (NHSN) procedure-associated (PA) module: surgical site infection (SSI) event. Atlanta: Centers for Disease Control and Prevention; 2013. http://www.cdc.gov/nhsn/PDFs/pscManual/9pscSSIcurrent.pdf. Accessed 14 Nov 2013.
21. Centers for Disease Control and Prevention. National Healthcare Safety Network (NHSN): About NHSN. Available at: http://www.cdc.gov/nhsn/about.html. Published November 2013. Accessed January 24, 2014.
22. Olsen MA, Nickel KB, Margenthaler JA, et al. Increased risk of surgical site infection among breast-conserving surgery re-excisions. *Ann Surg Oncol* 2015;22(6):2003–9.
23. Lu SM, Nelson JA, Fischer JP, et al. The impact of complications on function, health, and satisfaction following abdominally based autologous breast reconstruction: a prospective evaluation. *J Plast Reconstr Aesthet Surg* 2014;67(5):682–92.
24. Nickel KB, Fox IK, Margenthaler JA, et al. Effect of noninfectious wound complications after mastectomy on subsequent surgical procedures and early implant loss. *J Am Coll Surg* 2016 May;222(5):844–52.
25. Osman F, Saleh F, Jackson TD, et al. Increased postoperative complications in bilateral mastectomy patients compared to unilateral mastectomy: an analysis of the NSQIP database. *Ann Surg Oncol* 2013;20(10):3212–7.
26. American College of Surgeons. Frequently asked questions about ACS NSQIP. Available at: https://www.facs.org/quality-programs/acs-nsqip/joinnow/joinfaq. Published 2015. Accessed July 18, 2015.
27. Ju MH, Cohen ME, Bilimoria KY, et al. Effect of wound classification on risk adjustment in American College of Surgeons NSQIP. *J Am Coll Surg* 2014;219(3):371–81.
28. Nickel KB, Wallace AE, Warren DK, et al. Using claims data to perform surveillance for surgical site infection: the devil is in the details. In Battles JB et al (eds). *Advances in the Prevention and Control of HAIs.* Agency for Healthcare Research and Quality (US) Publication No. 14-0003: Rockville, Maryland; 2014,169–82.
29. Olsen MA, Fraser VJ. Use of diagnosis codes and/or wound culture results for surveillance of surgical site infection after mastectomy and breast reconstruction. *Infect Control Hosp Epidemiol* 2010;31(5):544–7.

## DISCUSSION

**Lippman, Miami:** Lovely talk and very interesting…. I would be interested in your comments…there is an epidemic going on in the United States in terms of the recrudescence of mastectomies which are more commonly being performed than are medically required and the use of bilateral mastectomy that is completely medically nonwarranted, while I suspect we'll be hearing more about that from Judy Garber in her talk. I am not talking about the high-risk genetic patients, I am talking about the necessary additional surgeries which are contributing substantially to these increased complication rates. And, in many cases, a non-foreseen tragedy of this is delaying lifesaving systemic therapy because of these infections, which would otherwise result in cure of patients.

BK-ACC-ACCA_2016-160073-Fraser.indd 56 29/06/16 5:16 PM

**Fraser, St. Louis:** Exactly, I think the biggest dilemma is that if people get a wound complication then they can't get their radiation or chemotherapy, sometimes for months, which is really a significant problem that will impact their outcome in a really negative way.

**Rosenthal, Iowa City:** That was a wonderful overview of the epidemiology of surgical site infections (SSIs) and the population you are looking at. One of the great things about claims data is its universal availability and the ability to look at large national populations. Some of the challenges are often, you know, related to the clinical specificity of the data and potential reliability of some of the diagnosis. I was wondering if there is much information out there on the sensitivity and specificity of claims data for looking at SSIs and if you have thoughts about this in terms of validating claims data for looking at SSIs and next approaches with regards to linking to EMR data.

**Fraser, St. Louis:** Great question…. We and others have done a lot of work using large administrative data, Medicare data, Medicaid data, private insured-data. Surgical site infections are one of the categories where there has been a significant amount of validation work. There is opportunity to make it even better when we do comparison chart reviews for sensitivity and then compare those with what was identified in the administrative data. So if anything, SSIs are still under-coded so patients who have mild infections, who have cellulitis get antibiotics and particularly are in the early period where they are under a bundle payment with a surgeon, may not be coded as having an SSI or other complication at all. The vast majority of these are picked up really because of readmissions and because they are associated with significant cost and additional procedures. Part of what we did to make it cleaner is that if there were not matching claims from the provider and from the facility, we reviewed each one of those independently to see why there was a disparity and we generally threw those cases out if there were things that didn't make sense. So we did a lot of cleaning of the data to get at an accurate data set. There has also been validation for a number of comorbidities in which there is a very strong association with using ICD 9 codes for some comorbidities. What it's not good for is coding things like obesity which is generally under-coded and some other comorbid conditions, like smoking status, are not well validated.

**Zeidel, Boston:** Wonderful talk. For a surgeon who does this sort of work, and I am definitely not a surgeon, you are going to want to go into quality improvement to try to figure out how to reduce this. So the real question is, (one lesson is of course you want to look later, but they are not going to look at insurance claims data) — how might we move from these insights into approaches that surgeons can use to say, let's do it this way, versus that way, and see how we can get these SSI numbers to come down, because the rates that you are showing are not a natural phenomenon and there are likely amenable to QI efforts.

**Fraser, St. Louis:** So we are actually doing a lot of that work as well and I think most hospitals now are very focused on prevention of health care–associated infections, and surgical site infections are a big target because they are one of the most common hospital-acquired infections. Typically, people are using bundled approaches, quality improvement approaches, rapid improvement events where they are looking at timing of prophylactic antibiotics, temperature control, glucose control, appropriate skin preps, and for these particular patients I think things like smoking sensation and then optimal wound care are very important. We've done a study recently looking at the risk prediction modeling that identified patients from rural areas, patients with substantial obesity, and patients who had diabetes were at higher risk. The patients who got home-healthcare not because of a pre-existing infection but because they were perceived to need home health for additional follow-up actually had lower rates of infection….so we may be able to really

BK-ACC-ACCA_2016-160073-Fraser.indd 57 29/06/16 5:16 PM

design a bundle in which high risk patients get additional post-operative outpatient care to reduce their risk of infection.

**Del Rio, Atlanta:** Vicky that's a great talk. I have two questions, one of them is: How about the microbiology, is this typical staph, *Staph epidermidis*, or are we seeing, you mentioned initially a typical rapid grower, something that we see here? And number two, what would be your recommendation as far as antibiotics, preoperative antibiotics, prophylactic? I mean, looking at this data you almost make me think that this is clean contaminated surgery rather than clean surgery and have you told your surgeons to change their approach in surgical prophylaxis?

**Fraser, St. Louis:** So most of the organisms are *Staph aureus* and *Staph epidermis,* but there have been outbreaks of rapidly growing mycobacteria. Those are typically associated with contamination of the implants, contamination of other fluids or gentian violet or other skin markers that are used for the tattooing that's done as part of the diagram or surgical procedure. And then about 20% of them are unusual gram-negative rods that cause infections and make it into the wound later because of drains, or suboptimal wound care. Right now, the recommendation for prophylactic antibiotics for this surgery is really a first-generation cephalosporin or if there is a high risk of having MRSA or significant penicillin allergy, then Vancomycin is used. Prophylactic antibiotic duration is really only supposed to be 24 hours, 3 doses of Ancef. What we found in our data is that most of these patients receive too many antibiotics for too long. All sorts of unusual combinations, and they leave the antibiotics on until the drains come out which sometimes are 2, 3, 4 weeks which increase the risk of antibiotic resistant organisms. We have shown that antibiotic-resistant infections are associated with increased risk of *Clostridium difficile* infection and so I think part of the strategy really has to be improving antibiotic use and focusing on this patient population to get narrow spectrum, short-course prophylactic antibiotics.

**Moore, New York City:** The major type of breast surgery we do in most of our hospitals is lumpectomy and there is great discussion when we have a close or positive margin and there is recent data showing that if the surgeons take extra margins or shaved margin at the time of lumpectomy we can markedly decrease, the re-excision or second lumpectomy rate. I think your data will be very important as we discuss how to decrease the second surgeries and I think it's going to be terrific.

BK-ACC-ACCA_2016-160073-Fraser.indd 58 29/06/16 5:16 PM